

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the claims

Claims 1-8, 10-12, and 15-25, were previously cancelled. Claim 14 is amended to correct claim dependency. This amendment is supported by previously pending claim 14 and does not introduce new matter. Upon entry of this amendment, independent claims 9 and 13, and dependent claim 14 are pending.

II. Objection to the specification and sequence listing

The Office withdrew the prior objection to the specification but reasserts an objection to the sequence listing for reciting SEQ ID NOS: 17-20. Action at page 2. Submitted herewith is a substitute sequence listing, which submitted removes the basis of the objection.

III. Obviousness type double patenting

The accompanying terminal disclaimer over U.S. Patent Application No. 11/585,172 overcomes the obviousness-type double patenting rejection asserted at pages 2-3 of the Action. This terminal disclaimer is submitted solely to advance prosecution, and without acquiescence to the rejection. Accordingly, Applicant respectfully requests withdrawal of the rejection.

IV. Rejection under 35 USC 112, first paragraph

A. The rejection

Claims 9, 13 and 14 are rejected as containing new matter. Action at pages 3-4. In particular, the specification and original claims allegedly do not support “a method employing an antibody which is humanized using the CDR(s) of PM-1 (FERM BP-2998).” Action at page 3. In particular, the Action states that the claims recite new matter because “the claims are now drawn to a method employing a genus of antibodies, *i.e.*, antibodies comprising PM-1 CDR(s) in any human antibody framework, that is not disclosed in the specification.” Action at page 4. Applicant respectfully traverses the rejection for reasons of record and in view of the following additional remarks.

B. Support for the subject matter

The specification at page 6, line 30, indicates that murine monoclonal PM-1 antibody is a preferred antibody for use in the present invention. The specification at page 10, line 17 to page 11, line 16 describes humanized and reshaped variants of murine monoclonal antibodies, how to make them, and states that preferred examples are the humanized variants of PM-1. *Id.* The specification also cites to WO 92/19759 for such humanized variants, and methods of making them. Specification at page 10, line 37 to page 11, line 2.

WO 92/19759, and the corresponding English language document, U.S. Patent No. 5,795,965, describe in detail methods for preparing humanized antibodies. *See* U.S. Patent No. 5,795,965, columns 6-15. Table 2 lists two different humanized variants of the PM-1 light chain variable region. *Id.* at columns 9-10. Table 3 lists six different humanized variants of the PM-1 heavy chain variable region. *Id.* at columns 11-12. Further details concerning the construction of PM-1 humanized variants are provided in Examples 2-4 (cols. 25-26), and 6-12 (cols. 28-38), for example.

Although specific “incorporation by reference” language was not used in regard WO 92/19759, this reference was published prior to the priority date of the present application and is, therefore, part of the knowledge of the person of ordinary skill in the art. *See Capon v Eshhar*, 418 F.3d 1349 (Fed. Cir. 2006).

Furthermore, the elements of the present claims are supported by the specification without requiring incorporation by reference from WO 92/19759. Thus, whether or not Applicant can incorporate by reference from WO 92/19759 is not determinative of the written description of the claims.

And even if Applicant sought to incorporate by reference from WO 92/19759, Applicant asserts that this would be proper under *Capon v Eshhar*, 418 F.3d 1349 (Fed. Cir. 2006) and *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006); *reh'g en banc den.*, 433 F.3d 1373 (2006); *cert den.* (Dkt No. 06-693, January 22, 2007). *See* Applicant’s Response filed February 23, 2007. More particularly, in the words of *Falkner*, “we hold that where, as in this case accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here “essential genes”), satisfaction of the written description

requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.” *Falkner* 448 F.3d at 1368.

Therefore, for at least these reasons, Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

Examiner Ewoldt is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to the Deposit Account.

Respectfully submitted,

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By Simon J. Elliott

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4726
Facsimile: (202) 672-5399

Simon J. Elliott
Attorney for Applicant
Registration No. 54,083